

FILED
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CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF OHIO

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,

INFORMATION

Plaintiff,

1:13MJ8015

v.

CR. NO.

MARWAN MASSOUEH,

Title 21, United States Code
Section 331(a), 352(f),
333(a)(1)

Defendant.

MAG. JUDGE McHARGH

The United States Attorney charges:

COUNT 1

1. Title 21, United States Code, Section 331(a) prohibits the introduction into interstate commerce of any drug that is misbranded. Under Title 21, United States Code, Section 352, a drug is misbranded if its labeling is false or misleading in any manner, or if its packaging or labeling fails to comply with the stringent requirements of the Federal Food, Drug, and Cosmetic Act and related regulations promulgated by the United States Food and Drug Administration (FDA). A drug may therefore be misbranded even if it is identical in composition to an FDA-approved drug (that is, a drug labeled and packaged in compliance with

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the FDA's standards) and even if it was made by the same manufacturer in the same facility as the FDA-approved version.

2. Defendant MARWAN MASSOUH, M.D., purchased and received prescription oncology drugs Zometa and Gemzar from Company #1, a foreign-based drug distributor located in Canada, between January 3, 2006, and March 31, 2009. Both drugs purchased by MASSOUH originated outside the United States and were never approved by the FDA for introduction into the United States.

3. Between January 3, 2006, and March 31, 2009, Defendant MARWAN MASSOUH, in the Northern District of Ohio, Eastern Division, caused the introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use; that is, they did not bear labeling indicating the drugs had been approved by the FDA for use in the United States.

In violation of Title 21, United States Code, Section 331(a), 352(f), 333(a)(1).


Ann C. Rowland
ANN C. ROWLAND
Chief, Major Fraud and Corruption Unit